

EC Certificate

Full Quality Assurance System

Certificate No.:
10369-2017-CE-RGC-NA-PS Rev. 0.0

Project No.:
PRJC-426250-2012-PRC-TWN

Valid Until:
23 AUGUST 2018

This is to certify that the quality system of:

Mouldex Co., Ltd.

22 Guang Fu S. Rd., Hsinchu Industrial Park 30351, Taiwan, R.O.C.

For design, production and final product inspection/testing of:

Intravascular Administration Set and Accessories

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 15 August 2017



For:
DNV GL NEMKO PRESAFE AS



Sholeh Gheissar

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.